

## REMARKS

### I. Claim Amendments

This amendment is being submitted concurrently with a Request for Continued Examination under 37 CFR §1.114, and Information Disclosure Statement submitted under 37 CFR §1.97 *et seq.* entry of which is respectfully requested.

Claims 2, 6 and 7 are currently pending in the application, claims 1, 3, 4 and 5 having been previously canceled.

Claim 2 is amended herein to more clearly indicate that the method is directed to increasing the rate of hair growth in a dog or cat subjected to direct hair removal. Support for this amendment may be found throughout the Specification, e.g., at paragraphs [0006] – [0008] and in the example.

Claim 2 has also been amended to clarify that the properly nutritious diet comprises selenium in the specified range. Support for this amendment may be found throughout the Specification, e.g., at paragraph [0004] and in the example. The range specified in claim 2 has been amended herein in keeping with an earlier amendment.

New claim 8 has been added to indicate that direct hair removal includes shaving or clipping. Support for this claim may be found in the Specification at paragraph [0002].

Claims 6 and 7 are canceled.

It is believed that no new matter has been added.

Following entry of the present amendment, claim 2 is currently pending, claim 8 is added and claims 6 and 7 are canceled in the application, reconsideration of which is respectfully requested.

### II. Claim Rejections under 35 USC §112

Claims 2, 6 and 7 stand rejected under 35 USC §112, first paragraph, for lack of enablement. In brief, the Examiner has argued that the Specification does not reasonably provide treatment of poor hair growth or alopecia over the entire scope of the claim where a dog or cat is receiving a properly nutritious diet. Specifically, the Examiner has alleged the following: the example does not show that selenium administration results in

new hair growth, thus the example does not provide evidence that administration of selenium will treat alopecia; the data in the example actually provides evidence that the claimed range is not effective to treat poor hair growth or alopecia in all animals, especially dogs, as beagle hair growth rates disclosed in the Specification are below the daily hair growth rate of 0.34-0.40 mm previously reported in Yu et al.; the example does not provide a “properly nutritious diet” if such term is defined to mean that the dog or cat was given a diet that met the selenium requirements of the dog or cat as the diet was deficient in selenium and had to be supplemented; the claims are broad and claim treatment of poor hair growth or alopecia without limitation as to cause; and no base line is provided for what would constitute poor hair growth in dogs or cats. In addition, according to the Examiner, given the state of the prior art, undue experimentation would be required in order to determine that administration of selenium in a “properly nutritious diet” would be effective in treating poor hair growth or alopecia in cats and dogs or was not otherwise the result of selenium toxicity or hypothyroidism which is treatable by selenium supplementation.

In response, in order to facilitate prosecution, Applicants have herein amended the claims of the instant invention to focus their claimed method on increasing the rate of hair growth in a dog or cat subjected to direct hair removal. As the Examiner’s rejection is with regard to the treatment of poor hair growth or alopecia, Applicants respectfully submit that this rejection is moot upon entry of the present amendment and reconsideration and withdrawal of this rejection is respectfully requested.

The Applicants note that the Examiner has alleged in his rejection that the working example does not provide a properly nutritious diet if “ ‘properly nutritious diet’ is defined to mean that the dog or cat was given a diet that met the selenium requirements of the dog or cat. The diet in the working example was deficient in selenium and had to be supplemented with selenium where needed.” Office Action of November 16, 2007 at pages 3-4. Applicants address this issue hereinbelow and direct the Examiner’s attention to pages 7-8 of this response. The Examiner has also alleged that the data in the example actually provides evidence that the claimed range is not effective to treat poor hair growth or alopecia in all animals, especially dogs, as beagle hair growth rates disclosed in the Specification are below the daily hair growth rate of 0.34-0.40 mm previously reported in

Yu et al. Applicants also address this issue in detail hereinbelow and respectfully direct the Examiner's attention to pages 14-15 of this response.

### **III. Claim Rejections under 35 USC §102/103**

#### **Rejection under 35 USC §102(b):**

Claim 2 is currently rejected under 35 USC §102(b) as being anticipated by Van Vleet, JAVA (1975) Vol. 166, No. 8 pp 769-774. Specifically, the Examiner has indicated that the term "controlling" encompasses reducing, maintaining, or increasing the rate of hair growth and that since the claim does not indicate whether the rate of hair growth is reduced, maintained or increased, the prior art process inherently reads on the claimed method as the amounts administered to the dogs fall within the claimed range of selenium of claim 2. In response to Applicants' previous arguments, the Examiner has alleged that the Applicant has not defined the term "properly nutritious diet" and that the dogs were fed a diet deficient in selenium, thus the term as used in the Specification can have deficiencies.

According to the Federal Circuit,

[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'

*In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (internal citations omitted). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). *See also*, MPEP §2112.

In this case, Applicants have previously argued that there is insufficient data in Van Vleet to support a rejection of claim 2 based on inherency. Specifically, the basal diet described in the cited reference was not only selenium deficient *but it was also*

*Vitamin E deficient.* The diets described in the cited reference contained *either* 30 IU alpha-tocopherol/kg (diet 2). 0.5 ppm selenite (diet 3) *or* 1.0 ppm selenite (diet 4). See, Van Vleet at page 770. None of the diets contained sufficient dietary amounts of *both* selenium and Vitamin E. As such, it is unclear whether an increase in hair growth rate would *necessarily* occur in the animals in Van Vleet as these animals were not fed a properly nutritious diet as such term is understood by one of skill in the art and as intended in the instant application.

The Examiner has argued that the Applicants fail to describe the term “properly nutritious diet” and that based on the Specification said diet can have deficiencies. Applicants respectfully disagree and submit that the meaning of the term “properly nutritious diet” is clear in the Specification as it is a term familiar to one of skill in the art. To this end, Applicants take this opportunity to point out that, as one of ordinary skill in the art might expect, prior to their inclusion in Applicants’ feeding study, the study dogs were fed and housed in accordance with strict animal welfare guidelines. As such, prior to inclusion in the hair growth study, these animals were fed a properly nutritious diet as that term is understood by one of skill in the art, i.e., a diet comprising sufficient levels of nutrients necessary to maintain the health and well-being of the animal, and as might be described in veterinary or trade journals, e.g., in official publications of the Association of American Feed Control Officials (AAFCO). As such, a properly nutritious diet, as understood by one of skill in the art, would not be deficient in any essential nutrient, including selenium.

As described in the Specification, upon selection into the hair growth rate study, the dogs were switched *temporarily* from a properly nutritious diet to a pre-test diet deficient in selenium (a torula yeast diet containing approximately 0.04 mg Se/kg (dry matter basis) by experimental design, i.e., in order to get the animals to a base line, or control, dietary selenium level. Depletion and repletion in this manner is a common technique in feeding studies and is familiar to one of skill in the art. After this pre-treatment period, however, varying amounts of selenium were then added to the basal diet in order to assay the effects of different concentrations of selenium on hair growth rate in the dogs. The amount of selenium in the experimental diets was determined by chemical analyses to be 0.034, 0.085, 0.123, 0.527, 1.025 and 5.045 mg Se/kg dry matter.

AAFCO nutrient profiles at the time of Applicants' feeding study list 0.11 mg Se/kg dry matter as the recommended maintenance minimum amount of dietary selenium for adult dogs. *See, e.g.*, Dzanis, J. Nutr. 124:2535S-2539S, 1994. Thus, Applicants respectfully submit that not only does Applicants' working example disclose several experimental diets that were *not* selenium deficient and therefore were "properly nutritious diets" as that term is understood by one of skill in the art, but also increased hair growth rate was detected in those dogs fed the diets comprising 0.123, 0.527 or 1.025 mg Se/kg dry matter. Not surprisingly, Applicants' data also indicated that no apparent clinical signs of selenium deficiency were observed in the dogs during the study period.

Several passages in the Specification further support Applicants' position that properly nutritious diets are described therein. For example, the Specification refers to "a composition which comprises about 0.1 to about 4.5 mg selenium/kg of diet on a dry matter basis, *the diet providing nutritional sustenance*". Specification at paragraph [0003], emphasis added. The Specification also mentions that the basal diet is "nutritionally complete and balanced for an adult dog *except for selenium*" which acknowledges that a properly nutritious diet would actually *not* be deficient in selenium. Specification at paragraph [0012], emphasis added.

As discussed above, in order to facilitate prosecution, Applicants have amended claim 2 in order to clarify that the method of the invention is focused on *increasing* the rate of hair growth in a dog or cat. In view of said amendment, in order to find a case of inherent anticipation, the dogs in Van Vleet must necessarily have had an *increase* in hair growth rate. As discussed above, the dogs in the cited reference were not fed a properly nutritious diet as the diets comprising 0.5 ppm Se or 0.1 ppm Se were *Vitamin E deficient*. Applicants respectfully submit that there is nothing in this reference that teaches that the Vitamin E deficient dogs necessarily had an increase in hair growth rate upon being fed the disclosed amounts of selenium. Indeed, as these dogs were not subjected to clipping or shaving or any other type of hair removal, there is really no way of knowing what kind of hair growth, if any, might have occurred in these animals, let alone that they would have demonstrated an *increase* in hair growth rate. Thus, Applicants respectfully submit that the Examiner has not provided the required basis in fact and/or technical reasoning to reasonably support his determination that an increase in

hair growth rate would *necessarily* occur in an animal fed the diets disclosed in Van Vleet, and thus Applicants respectfully request reconsideration and withdrawal of the rejection of claim 2 under 35 USC §102(b).

### **Rejections under 35 USC §103:**

The Examiner has again rejected claims 2, 6 and 7 under 35 USC §103(a) as being prima facie obvious over NAC, Nutrient Requirements of Cats (1986) ("NAC-NRC") in view of Dey et al., Current Science (1999) Vol. 77, No. 2, pp 276-280. According to the Examiner, the prior art teaches every element of the invention and suggests the treatment of poor hair growth or alopecia in cats as the prior art discloses a minimum requirement of 100 micrograms Se/kg diet and selenium levels in excess of 5 mg/kg are toxic in other species.

As such it would have been well within the skill of and [sic] one of ordinary skill in the art to restrict the amount of selenium in the diet to less than 5 mg/kg of diet to a minimum of 100 micrograms/kg of diet with the expectation that said amount would meet the selenium nutritional requirements of the cat while treating or reducing the risk of poor hair growth or alopecia due to selenium toxicity.

Office Action of November 16, 2007 at page 7. The Examiner has maintained this rejection despite Applicants' previous arguments, citing *KSR International Co. v. Teleflex Inc.*, 550 US \_\_\_, 82 USPQ 2d 1385 (2007) for the holding that there is no requirement that there be motivation to combine references.

Applicants respectfully submit that while the law regarding obviousness may have been modified with the holding in *KSR*, the Court did reiterate that obviousness is a question of law based on underlying factual inquiries as described in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). These are: determining the scope and content of the prior art, ascertaining the differences between the claimed invention and the prior art, and resolving the level of ordinary skill in the pertinent art. Secondary considerations such as commercial success, long-felt but unresolved need, failure of others and unexpected results may also be considered when present. *See also*, MPEP §2141.

Applicants respectfully submit that upon entry of the current amendments to the claims, the method of the present invention is directed to increasing hair growth rate in dogs and cats subjected to direct hair removal. As the cited references do not teach an *increase* in hair growth rate in cats, let alone describe hair growth after direct hair removal, every element of the Applicants' invention is not taught by the prior art, and thus Applicants respectfully request reconsideration and withdrawal of this rejection.

In addition, Applicants respectfully submit that the withdrawal of the rejection is appropriate given a careful reading of the cited art in view of the *Graham* factors. For example, with regard to the scope and content of the cited references, and the differences between the claimed invention and the prior art, Applicants respectfully submit that Dey et al. describes a study of heavy metal toxicity and trace-element deficiency in wild animals in India and mentions, among other things, that brittle hair and loss of long hair are known toxic effects of selenium. NAC-NRC suggests a minimum level of selenium that is desirable in cats, but does not describe a level of selenium that is toxic to cats. In contrast, as amended herein, the claims of the instant invention are not directed to treating poor hair growth or alopecia in a cat, let alone in a cat suffering from selenium toxicity.

Applicants also respectfully disagree with the Examiner with regard to the level of ordinary skill in the pertinent art. Specifically, Applicants respectfully submit that while hair growth studies involving humans and commercial animals such as sheep may be found in the literature, there has been much less interest in hair growth in companion animals such as dogs and cats with the result that relatively few studies have been published in this area. See, e.g., Gunaratnam, P. and Wilkinson, G.T., J. Small Animal Practice (1983) 24: 445-453. Thus, Applicants respectfully submit that a person of ordinary skill in the art (i.e., one who is presumed to be familiar with the relevant art at the time of the invention) would actually have limited information with regard to the effects of selenium on dogs and cats. Indeed, the Examiner's rejection suggests this fact, indicating that the NAC-NRC discloses that "selenium deficiency in cats has not been observed", and that while levels of selenium in excess of 5 mg/kg are toxic for many animal species, they "have not been reported to be toxic to the cat". Office Action of November 16, 2007 at page 6. Furthermore, although the Examiner cites Dey et al. for teaching that selenium toxicity in leopards, leopard cats and civet cats has resulted in

brittle hair loss and loss of long hair, Applicants note that a careful reading of the cited reference indicates that the same animals were also suffering from toxic levels of lead and mercury as well as from chromium deficiency. As such, in light of the abnormal levels of several heavy metals in these wild cats, Applicants respectfully submit that one of ordinary skill in the art reviewing Dey et al. would be unable to attribute any particular abnormal physiological effect seen in these animals directly to selenium toxicity.

The Examiner has made the following additional comment with regard to the rejection of the Applicants' invention:

One of ordinary skill in the art is not an automaton. One of ordinary skill in the art would recognize that providing selenium at amounts lower the [sic] 5 mg/kg of diet would result in increased hair growth. The prior art discloses that amounts higher than said amount results in hair loss. It is apparent that a condition of no hair is essentially zero hair growth which compared to a condition of hair being present is clearly an increase in the rate of hair growth.

Office Action of November 16, 2007 at page 8. Applicants respectfully disagree with the gist of this statement as understood by the Applicants. Specifically, Applicants respectfully submit that while one of skill in the art might suspect that decreasing the amount of selenium in the diet to less than 5 mg/kg of diet might cause a cessation of the *loss* of hair, there is no way of knowing what the nature or *rate* of any *new* hair growth might be, assuming that the hair would regrow at all. Applicants also respectfully disagree that it follows logically that any new hair growth should be considered an *increase in growth rate* under such circumstances. There is no scientific evidence to suggest that any hair that might grow back in an animal suffering from alopecia would do so at a rate greater than *the rate previously seen in the animal*, which is the proper variable for comparison. Applicants respectfully submit that the Examiner's interpretation that *any* hair growth compared to a condition of *no hair* is an *increase* in the *rate* of hair growth is inaccurate and Applicants respectfully submit that it is inappropriate to rely on this line of reasoning as a basis on which to reject the claims of the instant invention. It is particularly inappropriate in light of the Examiner's earlier arguments in which he distinguishes alopecia, or the absence or loss of hair, from the



condition in which the hair and hair follicle is still present. *See*, Office Action of November 16, 2007 at page 3.

In light of the above arguments, Applicants respectfully submit that rejection of the claims under 35 U.S.C. §103(a) as being unpatentable over NAC in view of Dey et al. is traversed and reconsideration and withdrawal of this rejection is respectfully requested.

Claims 2, 6 and 7 also remain rejected under 35 USC §103(a) as being unpatentable over Arthur et al. in view of Awadeh et al., Ahsan et al., Messenger, Daminet et al., NAC-NRS, NAC, NAC-NRD and NAC-NRC for reasons of record. Briefly, according to the Examiner, the prior art suggests a method for controlling the rate of hair growth or treating poor hair growth or alopecia in a dog or cat with about 0.5 to about 4.5 mg Se/kg because the cited art discloses that: selenium deficiency impairs thyroid hormone metabolism and conversion to T3, selenium deficiency results in T3 deficiency, T3 stimulates hair cell growth and/or metabolism, administration of thyroxine, which is converted to T3 by an enzyme which requires selenium, is effective in growing hair in rats, sheep and badgers, alopecia is a symptom of hypothyroidism and the disclosed selenium requirements for dogs, cats and sheep fall within or overlap the claimed range of about 0.5-4.5 mg/kg diet dry matter. Thus, according to the Examiner,

It would have been well within the skill of and [sic] one of ordinary skill in the art would have been motivated to administer similar amounts of selenium to dogs or cats with the expectation that selenium administration would control the rate of hair growth or treat poor hair growth or alopecia in animals in which poor hair growth or alopecia is due to hypothyroidism that is cause [sic] by selenium deficiency and treatable by selenium supplementation and to use levels of selenium below 5 mg/kg diet dry matter in order to reduce the risk of selenium toxicity.

Office Action of November 16, 2007 at pages 10-11.

In response to the Applicants' previous arguments that the animals are not selenium deficient and thus do not suffer from hair growth problems due to hypothyroidism due to selenium deficiency, the Examiner has alleged that the Specification does not state that the animals are not selenium deficient. The Examiner further points out that the animals were fed a selenium deficient basal diet in the working example, and that the claims are not limited to animals that are not deficient in selenium.

The Examiner reiterates that the term “properly nutritious diet” is not defined in the Specification, and since the only working example uses a “diet which was deficient in selenium absent addition to the same to the diet, the limitation “properly nutritious diet” does not exclude diets that are deficient in selenium”. Office Action of November 16, 2007 at page 11.

In response, and as discussed in detail above, Applicants respectfully submit that one of skill in the art would understand that the animals in which an increase in hair growth rate was observed were not selenium deficient other than during a short pre-treatment period, that the working example does include properly nutritious diets that are not selenium deficient and that several groups of dogs which were fed said diets demonstrated an increase in hair growth rate. In order to facilitate prosecution, claim 2 has been amended herein to more clearly indicate this fact.

The Examiner has also alleged that none of the amounts of selenium tested by Applicants exhibited a rate of hair growth that was at least the same as that reported as the average rate of hair growth for beagles, and that as the Applicants’ example does not provide evidence of new hair growth, the example fails to support the criticality of the claimed range for poor hair growth or alopecia (claims 3-5).<sup>1</sup> With regard to claim 2, the Examiner has alleged that any amount in the prior art would “control” the rate of hair growth, said term encompassing not only increasing hair growth but also reduction and maintenance of the rate of hair growth and the example fails to support the criticality of the claimed range. The Examiner also alleges that the example is not representative of the claimed invention as the diet given in the example was deficient in selenium and had to be supplemented with selenium.

As discussed above, Applicants have amended the claims of the instant invention to more clearly indicate that the method is directed to increasing the rate of hair growth in a dog or cat subjected to direct hair removal, thus mooted this rejection with regard to poor hair growth or alopecia. In addition, Applicants also respectfully direct the Examiner to arguments presented above supporting Applicants’ position that the instant

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<sup>1</sup> Applicants note that claims 3-5 were previously canceled by amendment filed March 26, 2007.

invention does in fact disclose properly nutritious diets which are not selenium deficient and that increased hair growth rates are observed in dogs fed diets comprising 0.123, 0.527 or 1.025 mg Se/kg dry matter.

In response to the Examiner's allegation that none of the amounts of selenium tested by Applicants exhibited a rate of hair growth that was at least the same as that reported as the average growth rate of hair for beagles, Applicants have previously argued that it is not scientifically appropriate to compare the growth rate previously reported with the growth rate reported by Applicants as the experimental conditions under which the previously reported rate was obtained were unknown. The Examiner has dismissed Applicants' arguments as not supported by evidence, arguing that "the authors in Yu et al. are the applicants and as such would be in the position to know the comparative conditions between the working example and the conditions under which beagle hair growth was measured in the Yu et al. reference". Office Action of November 16, 2007 at page 12.

In response, the Applicants would like to clarify that the average hair growth rate data referred to in Yu et al. (Journal of Animal Physiology and Animal Nutrition 2006, 90:146-151) was gleaned from the text, Muller and Kirk's Small Animal Dermatology, 6<sup>th</sup> Edition. See, pages 6, 65 of chapter 1 of this text provided herewith. This text cites as a reference, Al-Bagdadi, F.A., et al. Am J Vet Res 38:611-616. 1977. Upon closer inspection, however, the cited Al-Bagdadi reference does not actually describe the hair growth rate of beagle dogs and Applicants suspect that this reference was cited by the authors in error. Applicants believe that the correct citation may be found in Gunaratnam, P. and Wilkinson, G.T., J. Small Animal Practice (1983) 24: 445-453 which references Al-Bagdadi's Ph.D. thesis (Al-Bagdadi, F.A. (1975) *The Hair Cycle in Male Beagle Dogs*, Ph.D. Thesis. University of Illinois, Champaign, Illinois (hereinafter referred to as the "Al-Bagdadi dissertation")). Applicants have recently obtained the Al-Bagdadi dissertation, a copy of which is provided herewith.

Applicants respectfully submit that, although the Applicants might have observed a slower growth rate than described in the Al-Bagdadi dissertation, this does not lessen the validity of Applicants' data. Indeed, one of skill in the art might expect disparate results as different assay conditions, including season of the year, location on the body

from which the hair is sampled, and diet are known to influence hair growth rate. *See, e.g.,* Gunaratnam, P. and Wilkinson, W.T., *J. Small Anim Pract* (1983) 24, 445-453.

In this case, as originally suspected, a review of the Al-Bagdadi dissertation indicates several major differences between Applicants' study and Al-Bagdadi's study. *See, Al-Bagdadi dissertation, Materials and Methods section, pages 29-42.* These differences could have significantly impacted the hair growth rate reported, therefore Applicants respectfully submit that Al-Bagdadi's study data is not comparable to Applicants'. For example, Al-Bagdadi studied puppies and young adults (< 3 years) and only males while Applicants used older dogs (> 7 years), both male and female and most of these were either spayed or neutered. Although Applicants are unsure of the impact that age and sex hormones may have on the rate of hair growth in beagle dogs, both age and sex hormones are known to have an effect on hair growth in humans.

Al-Bagdadi's dogs were kept outside during the day with the result that a seasonal change on hair growth rate was evident in his study; a daily hair growth rate in summer of 0.34 mm and 0.40 mm in winter was recorded. In contrast, Applicants' dogs were kept inside, under experimental conditions that included controlled temperature (21 °C) and light cycle.

Al-Bagdadi's dissertation provides only basic information regarding what was fed to his dogs. Specifically, he does not report micronutrients (minerals and vitamins) in the food used in his study. Applicants note that several of these nutrients, e.g., zinc and copper, are important for hair growth. Thus, unlike Applicants' dogs, it is unclear from Al-Bagdadi's dissertation whether his dogs received a balanced amount of these nutrients.

Al-Bagdadi's sample size was relatively small - only 9 dogs in total (3 groups of 3) were studied. In contrast, Applicants used 36 dogs in total (6 groups of 6). Applicants respectfully submit that, given the degree of variation in hair growth measurement, Al-Bagdadi's data on hair growth rate may be less representative of the true average hair growth rate in a beagle.

In addition, the measuring methods employed in a hair growth rate study can contribute to differences in observed growth rates. One of skill in the art knows that measuring hair growth rate is particularly difficult and known measurement techniques

can introduce error. For example, hair growth rate may be measured by shaving an area, reshaving the area as new hair grows back, collecting the shavings and directly measuring a random sample of shaved hairs using a microscope. *See, e.g.,* Comben et al., Br Vet J 1951 May 107 (5) 231-235; Gunaratnam, P. and Wilkinson, W.T., J. Small Anim Pract (1983) 24, 445-453. This technique is not entirely reliable, however, since not only is it subject to human error given the tedious nature of the process, it is also possible during shaving to recut a shaven hair, creating artificially short pieces. In fact, Al-Bagdadi's dissertation indicates that the author tried the method described in Comben (1951) but rejected it given the "extreme variation" in hair segments after shaving. Al-Bagdadi attributed this variation as being the result of sampling a mosaic, or mix, of hairs growing at different rates, i.e., hairs in anagen, catagen and telogen. As a result, Al-Bagdadi chose to measure only the *longest* hairs (i.e., hairs in anagen) in the sample region in order to determine "the most rapid rate of growth". *See*, Al-Bagdadi dissertation at page 34. Specifically, using a ruler against the skin, Al-Bagdadi only measured 10 hair shafts and these 10 hair shafts were the fastest growing ones.

In contrast, given the imprecise nature of the commonly used methods to measure hair growth rate, Applicants used a more sophisticated technique, taking pictures of new hair growth (using slides to press the hair to the skin in order to minimize errors caused by the angle formed between standing hair and skin), and scanning the negatives with a computer and employing image analyzing software to measure the length of hair in the image. *See*, Specification at paragraph [0013]. Unlike Al-Bagdadi, the Applicants measured all hairs in the camera view area, which typically included more than 50 hairs, thus Applicants' data represent an average of hair growth rate of all hairs counted, including slower growing hairs. Thus, Applicants respectfully submit that Applicants' hair growth rate data actually may be *more accurate* than the rate previously reported by Al-Bagdadi.

Taken together, even though the average hair growth rate reported by Al-Bagdadi may be greater than the rate reported in the instant invention, Applicants respectfully submit that their data is reliable and a statistically significant increase in hair growth rate was observed in their carefully controlled and properly executed feeding study. Thus, Applicants respectfully submit that it is inappropriate for the Examiner to reject the

claims of the instant invention based upon the assumption that Applicants' invention is ineffective or that the example is not commensurate in scope with the claims.


In light of the above arguments, Applicants believe that the rejection of the claims under 35 USC §103(a) as being unpatentable over Arthur et al. in view of Awadeh et al., Ahsan et al., Messenger, Daminet et al., NAC-NRS, NAC, NAC-NRD and NAC-NRC is inappropriate and Applicants respectfully request reconsideration and withdrawal of this rejection.

#### **IV. Conclusion**

In summary, given the amendments to the claims and in view of Applicants' responses to the outstanding rejections provided hereinabove, Applicants believe that the Examiner's rejections under 35 USC §§112, 102 and 103 have been obviated or overcome. Reconsideration of the application as amended herein and allowance of the pending claims are respectfully requested.

If the Examiner feels that a telephonic interview would advance prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided below.

Respectfully submitted,



Date: March 17, 2008

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